

**Notice of Allowability**

Application No.

10/080,876

Examiner

Shobha Kantamneni

Applicant(s)

WALKER ET AL.

Art Unit

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**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/07/2005.
2. ☒ The allowed claim(s) is/are 15, 17, 18, 20, 22.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input type="checkbox"/> Examiner's Amendment/Comment                               |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material                     | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance   |
|  | 9. <input type="checkbox"/> Other _____.   |

### **EXAMINER'S STATEMENT OF REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

The present invention is directed to a method of reducing circulating fatty acids in adipose tissue in a patient in need thereof comprising determining reductase activity of 11-Beta HSD1 in adipose tissue, determining whether a compound or composition inhibits said reductase activity of 11-Beta HSD1 in adipose tissue, and administering to said patient said compound or composition which inhibits reductase activity in adipose tissue.

The closest prior art reference, Walker et al. (Walker et al. Clinical Endocrinology 1993, pages 221-227) discloses that carbenoxolone inhibits both 11-beta reductase activity, and 11 beta-dehydrogenase activity of 11-Beta HSD1, and indicates that 11 beta-reductase activity is predominant in liver and the 11 beta-dehydrogenase activity is predominant in kidney, so that inhibition by carbenoxolone would increase cortisol levels in kidney and decrease cortisol levels in liver. The present invention is specific to the reductase activity of 11 beta-HSD1 in adipose tissue. The present invention is also specific to lowering of circulating fatty acids levels in adipose tissue in a patient in need thereof by inhibiting the reductase activity of 11-Beta HSD1. Walker et al. do not teach or suggest that inhibition of 11 Beta-HSD1 in adipose tissue results in inhibition of reductase activity and thus results in lowering of circulating fatty acids concentration in adipose tissue. There is no teaching in Walker et al. and the prior art in its entirety to select adipose tissue as targets for 11 Beta-HSD1 where reductase activity is predominant. Thus, there would not be any motivation to inhibit 11 Beta-HSD1 in

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adipose tissue because a person of ordinary skill in the art at the time of invention would not expect that this would lower circulating fatty acids in adipose tissue.

Thus, the instant method of reducing circulating fatty acids in adipose tissue in a patient in need thereof comprising determining reductase activity of 11-Beta HSD1 in adipose tissue, determining whether a compound or composition inhibits said reductase activity of 11-Beta HSD1 in adipose tissue, and administering to said patient said compound or composition which inhibits reductase activity in adipose tissue is novel, and further provides the use of inhibitors of 11 beta-HSD1 in patients in need of lowering circulating fatty acids levels in adipose tissue.

Thus, the method of the present invention is novel and unobvious over the prior art.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

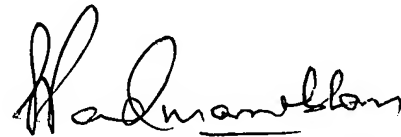
Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read "S. Padmanabhan", with a horizontal line underneath the name.

**SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER**